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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/803,687      | 03/09/2001  | David T. Scadden     | 0492479-0018        | 7008             |

7590 12/23/2004

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| EXAMINER |
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KATCHEVES, KONSTANTINA T

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 12/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/803,687

**Applicant(s)**

SCADDEN ET AL.

**Examiner**

Konstantina Katcheves

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-32,34-37,42-45 and 75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32,34-37,42-45 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 1-32, 34-37, 42-45 and 75 are pending in the present application.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 October 2004 has been entered.

#### ***Response to Amendment***

Claims 1, 3, 4, 6-11, 13, 15-18, 20, 22-29, 30, 33, 36-41, 43-45 and 75 stand rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (US Patent No. 5,958,769).

Claims 1-45 and 75 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. as applied to claims 1, 3, 4, 6-11, 13, 15-18, 20, 22-29, 30, 33, 36-41, 43-45 and 75 above, and further in view of Waldman et al. (Cancer Research Vol. 55 1995, cited in prior action).

Claims 27 and 75 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other inhibiting agents, does not reasonably provide enablement for antisense agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

***Response to Arguments***

Applicant has not provided new arguments filed with the Request for Continued Examination filed on 15 October 2004. Applicant has not addressed the examiners rebuttal to Applicant's afterfinal remarks found in the Advisory Action mailed 8 September 2004. For the purposes of clarity those remarks are repeated and expanded upon below.

Applicant's present amendment and remarks filed on 16 August 2004 fail to overcome the pending rejections under 35 U.S.C. 102, 35 U.S.C. 103 and the pending rejection under 35 U.S.C 112, first paragraph.

Claims 1, 3, 4, 6-11, 13, 15-18, 20, 22-29, 30, 33, 36-41, 43-45 and 75 stand rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (US Patent No. 5,958,769).

With regard to the rejections under 35 U.S.C. 102 that the prior art fails to provide an enabling disclosure. It is noted that the test for "enabling disclosure" is whether the public was in possession of the claimed invention before the date of invention. See MPEP 2121.01 "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." See MPEP 2101.01 citing *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. cir. 1985).

Roberts et al. discloses that the p21 along with p27 could be inhibited to increase the proportion of proliferating cells in a population. The fact that Roberts et al. disclosed other protein targets thought to be involved in cell cycle control and did not try every combination does not render the invention invention inoperable. Indeed, Roberts et al. show that inhibition of

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p27 increases the proportion of proliferating cells in a population there is no reason to conclude that inhibiting another target protein involved in cell cycle control would render the disclosure inoperable. Moreover, Roberts et al. disclose antagonists of p21 such that one of skill in the art would not have to engage in undue experimentation to either make or use the method claimed.

Claims 1-45 and 75 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. as applied to claims 1, 3, 4, 6-11, 13, 15-18, 20, 22-29, 30, 33, 36-41, 43-45 and 75 above, and further in view of Waldman et al. (Cancer Research Vol. 55 1995, cited in prior action).

Applicant asserts in the remarks filed 16 August 2004 that independent claims 1, 3, and 30 only recite a decrease in p21 activity and do not recite a decrease in both p21 and p27 activity. Applicant should note that the claim recites open language and is therefore not limited to an increase in only p21 activity. Applicant's arguments regarding the propriety of the rejection under 35 USC 103 rely on those arguments set forth with regard to Roberts et al. which have been addressed above.

Applicant also argues that even if Roberts et al is applicable as art, it fails to disclose the use of stem or progenitor cells in the method. This argument has been previously presented and rebutted with regard to the 102 rejection over Roberts et al. As stated in the final rejection, the cell populations include stem cells, progenitor cells, fibroblasts, myeloblasts, neurons, epithelial cells, hematopoietic progenitor cells, granulopoietic and embryogenic cells. See column 2, lines 64 to column 3 lines 11, column 20, and example 5.

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Claims 27 and 75 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other inhibiting agents, does not reasonably provide enablement for antisense agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues in the remarks filed 16 August 2004 that a manuscript by the inventors discloses that the transient reduction of p21 levels in cells treated with specific RNAi constructs targeting p21 obviates the rejection under 35 USC 112, first paragraph. The manuscript Zhang et al. cited by Applicant fails to overcome the present rejection. First, the manuscript cited by Applicant is undated. According to MPEP 2164.05(a) the specification must be enabling as of the filing date sought because the state of the art is "not static in time." For example, a non-enabling disclosure filed in 1995 may be enabling if that same disclosure is filed in 2000. The examiner has met her burden and cited references to establish the state of the art. Thus, to overcome the present rejection Applicant must present convincing evidence, *e.g.* affidavit, declaration, *etc.*, that the invention is enabled.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves  
Examiner  
Art Unit 1636



JAMES KETTER  
PRIMARY EXAMINER